the translations. Ten to fifteen cognitive debriefing interviews were conducted in each country. Interviewees reported the measure to be easy to understand and complete and that the content was relevant without missing important issues. **CONCLUSIONS:** The standards set by the existing UK version of the QoL-AGHDA are high with internal consistency and test-retest reliability above 0.90. Construct validity was also demonstrated by the measure's ability to distinguish between patients according to self-perceived general health and by correlating scores with those on the General Well Being Index (> 0.70). Completed validations have obtained a similar psychometric quality. Similar studies are underway to evaluate the formal construct validity and reproducibility of these new language versions.

PDB90

USEFULNESS OF THE HYPOGLYCEMIA PERSPECTIVES QUESTIONNAIRE (HPQ) IN MANAGEMENT OF PATIENTS WITH TYPE 2 DIABETES

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OBJECTIVES: Assessment of patient's perspectives of hypoglycemia burden may be of value to provide adequate management of type 2 diabetes (T2D) patients. The Hypoglycemia Perspectives Questionnaire (HPQ) is a new multidimensional instrument assessing patient's experience of hypoglycemia. The goal of this study was to test the practicability and utility of HPQ-Russian version (HPQ-R) by means of its psychometric performance. **METHODS:** A total of 200 T2D patients receiving oral hypoglycemic therapy (59% – metformin; 41% – metformin plus vildagliptin or sulphonylureas, SU) were enrolled in the study: male/female 71/129; mean age – 58.7 yrs; mean disease duration – 4.1 yrs. Mean HbA1c level was 7%. All the patients completed HPQ-R at baseline and after 2-3 months of treatment. Patients and physicians were interviewed to test practicability of the instrument. Construct validity, reliability and sensitivity of the HPQ-R were assessed to provide its utility. **RESULTS:** Both patients and physicians acknowledged the comprehensiveness of the tool for revealing hypoglycemia-related problems; physicians used information from it for their decision-making. It was easily understood by, and administered to patients: 2.8% of missing values. An exploratory factor analysis revealed a strongly dimensional instrument (explained 70% of total pooled variance), with Chronbach alphas ≥0.9 for 6 out of 7 scales. Reproducibility of the tool was shown by comparing HPQ-R scores at two time-points for patients with effective HbA1c control receiving metformin plus vildagliptin: r=0.53–0.87 for 5 scales ($p<0.05$). HPQ-R scores were lower in patients with hypoglycemia events than in patients without hypoglycemia as well as in patients with severe hypoglycemia than in patients with non-severe hypoglycemia ($p<0.05$). Increased occurrence of hypoglycemia events and worsening of scores for 4 HPQ scales was shown after switch from monotherapy to therapy metformin plus SU ($p<0.05$). **CONCLUSIONS:** Thus, the HPQ-R is a practical and useful tool for comprehensive assessment of hypoglycemia experience in T2D patients.

PDB91

BENEFITS OF VILDAGLIPTIN PLUS METFORMIN COMBINATION THERAPY IN TYPE 2 DIABETES MELLITUS (T2DM) FROM PATIENT'S PERSPECTIVE: QUALITY OF LIFE (QOL) AND HYPOGLYCEMIA BURDEN ANALYSIS

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OBJECTIVES: Patients' preferences and evaluation of treatment benefits/risks from patient's perspective are increasingly being considered in decision-making regarding treatment option. The goal of this prospective, open, observational study was to evaluate QoL and hypoglycemia burden in T2DM patients treated with vildagliptin and metformin as compared to those treated with sulphonylureas (SU) and metformin. **METHODS:** A total of 194 T2DM patients previously on oral monotherapy were enrolled in the study. 111 patients were selected by their treating physician to receive vildagliptin and metformin (cohort 1 – mean age 58 yrs; male/female 43/68) and 83 patients – SU and metformin (cohort 2– mean age 58.6 yrs; male/female 27/56). Patient-reported outcomes were assessed at base-line and after approximately 3 mo using the SF-36 and the Hypoglycemia Perspectives Questionnaire (HPQ). For comparisons adjustment for age, sex, disease duration, complications and comorbidities was made. **RESULTS:** QoL parameters for all SF-36 scales were significantly higher in cohort 1 as compared to cohort 2 after 3 mo of therapy ($p<0.01$). Switch to vildagliptin plus metformin therapy was accompanied with remarkable increase of Integral QoL Index ($p<0.0001$) whereas no changes of Integral QoL Index were observed after switch to SU plus metformin. After 3 mo of combination therapy the number of self-reported symptomatic hypoglycemic events was 16% in cohort 1 versus 70% in cohort 2; 12% of pts had severe hypoglycemic events in cohort 2. SU plus metformin therapy was accompanied with significant hypoglycemia burden – after switching worries, awareness and symptom concern increased ($p<0.001$). No changes were observed in cohort 1. The changes in glycemic control were the same in both cohorts: DHbA1c=0.8%. **CONCLUSIONS:** Benefits of vildagliptin plus metformin combination therapy in terms of improved QoL and reduced hypoglycemia burden in T2DM patients were shown. This therapy is an effective and preferable treatment in daily medical practice from patient's perspective.

PDB92

PRELIMINARY TESTING OF THE SAGIT TOOL: A TOOL TO HELP ENDOCRINOLOGISTS IN THEIR MANAGEMENT OF PATIENTS WITH ACROMEGALY IN CLINICAL PRACTICE

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OBJECTIVES: Acromegaly is a rare, chronic, hormonal disorder caused by excessive growth hormone (GH) and insulin-like growth factor 1 (IGF-1) production resulting predominantly from pituitary adenoma. The objective was to test endocrinologist acceptability of the newly developed SAGIT tool in clinical practice. **METHODS:** SAGIT (**S**igns and symptoms - **A**ssociated comorbidities - **G**H concentration level – IGF-1 – **T**umour) is a Clinician-Reported Outcomes (ClinROs) tool developed with international experts in acromegaly; it allows patient classification and description in a standardised manner. The tool was pre-tested for acceptability, understanding and ease of use with practicing endocrinologists in France, Germany, UK, Spain, Italy and Brazil (n=2 per country) using the PRAgmatic Content and face validity Test (PRAC-Test). The endocrinologists completed the SAGIT tool prior to and following an intervention (therapeutics or surgery) for three patients each (n=36). Once completed, a one-hour phone interview was conducted with each endocrinologist to collect their feedback on the tool. **RESULTS:** The tool was well accepted and deemed concise (n=11) and informative (n=10) by the endocrinologists. Several points were raised that illustrate its usefulness in clinical practice, including the removal of the subjectivity when assessing the disease severity, the possibility of rapid evaluation of the control/progression of acromegaly or of a treatment response, and the possibility for standardisation across countries. Key recommendations for improvements were the need to include: 1) instructions to facilitate the understanding and the use of the tool; 2) definitions of rules and recommendations for patient management; and 3) addition of other signs and symptoms and further details about tumour size to better reflect their clinical cases. **CONCLUSIONS:** SAGIT is a useful tool for endocrinologists to accurately stage and classify acromegaly patients in clinical practice. It is currently being piloted in a cross-sectional study. Validation of scoring rules will confirm the utility of the tool to improve patient management.

PDB93

A DISCRETE CHOICE EXPERIMENT TO EVALUATE BLOOD GLUCOSE METER PREFERENCES IN PEOPLE WITH TYPE 1 AND TYPE 2 DIABETES IN THE UNITED KINGDOM

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OBJECTIVES: Regular self-monitoring of using a blood glucose meter helps diabetic patients to adjust their management strategies proactively, thus avoiding diabetic complications which place a burden on health care resources. The aim of this study was to elicit diabetic patients' preferences for different blood glucose meter attributes. **METHODS:** A cross-sectional, web-based survey of UK patients with Type 1 and type 2 diabetes was conducted in January 2013 and preferences for five key attributes associated with blood glucose meters were estimated using a discrete choice experiment (DCE) framework. A foldover design and optimised orthogonal differences were considered, but the final choice experiment was a Bayesian d-efficient design. Responses were analysed using a conditional logit model in STATA 12.1. **RESULTS:** Out of 447 responses, 406 (90.83%) patients were suitable for inclusion in the DCE analysis. Statistically significant differences ($p<0.05$) were found between the Type 1 and Type 2 sub-groups when comparing responder characteristics (years diagnosed, age, tests per day, number of comorbidities). Regarding glucose meter attributes, Type 1 respondents considered the 'time to test' to be the most critical factor and were willing to trade a compact device (2.61 units), or convenience (1.37 units) for a device that could produce test results in under 30 seconds. Type 2 respondents preferred the low maintenance attribute and were most willing to trade a compact device (2.72 units) or convenience (1.37 units) for this attribute. **CONCLUSIONS:** This is the first DCE to examine the impact of blood glucose meter attributes on blood glucose meter choice and adherence. Devices that provide value added features such as offline storage of data and additional data analysis will be valued by both Type 1 and Type 2 patients whereas a compact device is less valued.

PDB94

GROWTH MIXTURE MODELING (GMM) TO DETERMINE TREATMENT EFFECTS OF CANAGLIFLOZIN VERSUS SITAGLIPTIN ON WEIGHT-RELATED QUALITY OF LIFE (WRQOL) IN SUBJECTS WITH TYPE 2 DIABETES MELLITUS (T2DM)

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OBJECTIVES: Canagliflozin is a sodium glucose co-transporter 2 inhibitor developed for T2DM. GMM was used to evaluate the effects of canagliflozin versus sitagliptin on WRQoL in subjects with T2DM. **METHODS:** Data were from 2 multinational, randomised, double-blind, Phase 3 trials: 1) subjects inadequately controlled with metformin (N=1,284) receiving canagliflozin 100 or 300 mg, sitagliptin 100 mg, or placebo for 26 weeks with a 26-week extension (placebo switched to sitagliptin; dual therapy); and 2) subjects inadequately controlled with metformin plus a sulphonylurea (N=755) receiving canagliflozin 300 mg or SITA 100 mg for 52 weeks (triple therapy). WRQoL was assessed using the Impact of Weight on Quality of Life-Lite (IWQOL-Lite) questionnaire. GMM was used to assess heterogeneity within samples to identify data-driven subgroups with differential changes in IWQOL-Lite total scores. **RESULTS:** In both trials, GMM identified 2 subgroups per treatment arm: "subgroup 1" (81% and 87% of total trial samples) started with high scores (~85 points), while "subgroup 2" (19% and 13% of total trial samples) started with low scores (44-53 points). Subgroup 1 scores remained high throughout both trials for all treatments. For the dual-therapy trial, subgroup 2 subjects treated with canagliflozin 100 or 300 mg had improvement (2.1 and 5.4 points, respectively), while those treated with sitagliptin 100 mg had declining scores (–4.0 points) over the course of the trial ($P<0.05$). For the triple therapy trial, all subgroup 2 subjects improved; improvement was significantly greater with canagliflozin 300 mg versus sitagliptin 100 mg (19.6 vs 4.8 points; $P<0.05$). In both trials, there were significant differences between the subgroups based upon baseline demographic, clinical, and patient-reported characteristics. **CONCLUSIONS:** GMM applied to these trial data enabled identification of treatment effects that were masked by standard statistical techniques. Heterogeneity should be considered when analysing WRQoL data.